

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 33. (currently amended) A method of preparing fenofibrate microparticles, including a particle size reduction process for reducing the initial average particle size, [such as sonication, homogenization, milling, microfluidization, recrystallization, and precipitation, or a combination thereof,] the method comprising the steps of:

(1) mixing the fenofibrate particles with (a) a natural or synthetic phospholipid and (b) at least one non-ionic, anionic or cationic surfactant, prior to or during the particle size reduction process, and thereafter

(2) applying energy to the mixture sufficient to produce fenofibrate microparticles having a volume-weighted mean particle size value that is about 50% smaller than particles produced without the presence of the surfactant using the same energy input.

Claim 34. (previously presented) The method of claim 33, wherein step (1) further comprises mixing the fenofibrate particles with (a) at least two phospholipids and at least one surfactant, (b) a phospholipid and at least two surfactants, or (c) at least two phospholipids and at least two surfactants.

Claim 35. (previously presented) The method of claim 33, wherein the mixture comprises an alkyl aryl polyether sulfonate, a sorbitan fatty acid ester, a polyoxyethylene sorbitan fatty acid ester, a polyoxyethylene stearate, polyethylene glycol, benzalkonium chloride, cetyltrimethylammonium bromide, lauryldimethylbenzylammonium chloride, or a combination of any thereof.

Claim 36. (previously presented) The method of claim 33, wherein the phospholipid is selected from the group consisting of phosphatidylcholine, phosphatidylethanolamine, phosphatidylserine, phosphatidylinositol, phosphatidylglycerol, sphingomyelin, dimyristoyl phosphatidylglycerol sodium salt, phosphatidic acid, lysophospholipids, and combinations thereof.

Claim 38. (previously presented) The method of claim 33, wherein the fenofibrate particles are 5-100 μm in size, such that the fenofibrate microparticles have a volume-weighted mean particle size value that is about 80% smaller than particles produced without the presence of the surfactant using the same energy input.

Claim 39. (previously presented) The method of claim 33, wherein the mixture comprises a surfactant in a concentration above its critical micelle concentration.

Claim 40. (previously presented) The method of claim 33, wherein the method comprises preparing a pharmaceutically acceptable composition from the composition of fenofibrate microparticles.

Claim 41. (previously presented) The method of claim 40, wherein the method comprises preparing a suspension of the fenofibrate microparticles.

Claim 42. (previously presented) The method of claim 41, wherein the method comprises preparing a powder from the composition by lyophilization, fluid drying, or spray drying.

Claim 45. (previously presented) The method of claim 42, wherein the method comprises preparing an orally administrable tablet from the powder.

Claim 46. (previously presented) The method of claim 42, wherein the composition is spray dried and the surfactant consists of polyvinylpyrrolidone or a combination of polyvinylpyrrolidone and one or more additional surfactants.

Claim 47. (previously presented) The method of claim 46, wherein the composition is further converted into granules.

Claim 48. (previously presented) A composition comprising fenofibrate microparticles produced by the method of claim 33.

Claim 50. (previously presented) A pharmaceutically acceptable composition comprising granules produced by the method of claim 47.

Claim 51. (New) The method of claim 33, wherein the particle size reduction process includes sonication, homogenization, milling, microfluidization, recrystallization, and precipitation, or a combination thereof.

Claim 52. (New) The method of claim 33, wherein the surfactant is selected from the group consisting of casein, tragacanth, enteric resins, cholesterol esters, polyoxyethylene fatty alcohol ethers, polyoxyethylene fatty acid esters, sorbitan esters, glycerol monostearate, polyethylene glycols, cetyl alcohol, cetostearyl alcohol, stearyl alcohol, poloxamers, polaxamines, polyvinyl alcohol, polyvinylpyrrolidone, potassium laurate, triethanolamine stearate, sodium lauryl sulfate, alkyl polyoxyethylene sulfates, sodium alginate, dioctyl sodium sulfosuccinate, negatively charged glycerol esters, quaternary ammonium compounds, chitosans, colloidal clays, sodium dodecylsulfate, sodium deocycholate, and combinations thereof.

Claim 53. (New) A method of preparing fenofibrate microparticles which includes reducing the initial average particle size by sonication, homogenization, milling,

microfluidization, recrystallization, and precipitation, or a combination thereof, the method comprising the steps of:

(1) mixing the fenofibrate particles with (a) a natural or synthetic phospholipid and (b) at least one non-ionic, anionic or cationic surfactant, prior to or as the initial average particle size is reduced; and

(2) applying energy to the mixture sufficient to produce fenofibrate microparticles having a volume-weighted mean particle size value that is about 50% smaller than particles produced without the presence of the surfactant using the same energy input.

Claim 54. (New) The method of claim 53, wherein the surfactant is selected from the group consisting of casein, tragacanth, enteric resins, cholesterol esters, polyoxyethylene fatty alcohol ethers, polyoxyethylene fatty acid esters, sorbitan esters, glycerol monostearate, polyethylene glycols, cetyl alcohol, cetostearyl alcohol, stearyl alcohol, poloxamers, polaxamines, polyvinyl alcohol, polyvinylpyrrolidone, potassium laurate, triethanolamine stearate, sodium lauryl sulfate, alkyl polyoxyethylene sulfates, sodium alginate, dioctyl sodium sulfosuccinate, negatively charged glycerol esters, quaternary ammonium compounds, chitosans, colloidal clays, sodium dodecylsulfate, sodium deocycholate, and combinations thereof.